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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,097	08/23/2001	Michael Hershfield	1579-527	7948
23117	7590	03/16/2005	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/762,097

Applicant(s)

HERSHFIELD ET AL.

Examiner

Charles L. Patterson, Jr.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/7/03, 3/24/04 and 3/29/04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 is/are allowed.
- 6) ☒ Claim(s) 2, 6-10, 12, 14 and 16-25 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 11, 13 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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After consultations regarding the petitions<sup>and 3/24/04</sup> filed 11/7/03<sup>^</sup>, the examiner agrees that the prior art cited in the petition decision mailed 9/10/03 as a reason for holding lack of unity of invention does not apply to the instant claims and that apparently claims drawn to both the nucleic acid and protein should be examined. The restriction requirement is hereby <sup>withdrawn</sup> ~~rejoined~~ and claims 2-25 will be examined. As this was all that was requested by the petitions<sup>^</sup>, the petitions<sup>filed 11/7/03 and 3/24/04 are</sup> is now moot.

J. Burke  
TC 1600  
SPA E

Claims 6-9, 12 and 19-21 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-9 and 20-21 are incorrect in the recitation of "molecule coding the [a] recombinant uricase". The recitation should either be "molecule encoding the [a] recombinant uricase" or else "molecule coding for the [a] recombinant uricase".

Claim 12 is indefinite and confusing in the recitation of "nucleic acid molecule of claim 2". Claim 2 is drawn to a protein, not a nucleic acid molecule. Perhaps claim 6 was intended.

Claim 19 is confusing and indefinite in the recitation of "a mammalian uricase" on line 4. Does applicant wish to refer to the mammalian uricase in the first part of the claim or some unknown uricase? If this is the case then the instant recitation should be "the mammalian uricase" or "said mammalian uricase". As the claim now stands it refers to any mammalian uricase whatsoever and that would be confusing given the recitation of "wherein said recombinant uricase protein does not include..."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 6, 12, 14, 16-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1-4 and 8-11 and the embodiments of these sequences, does not reasonably provide enablement for the breadth of the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches that the uricases of SEQ ID NO:1-4 and 8-11 retain significant activity with reduced antigenicity but nothing is taught concerning the embodiments of the instant claims. The instant claims are much broader than the embodiments taught by the specification to have significant activity but reduced antigenicity. These claims read on a uricase made from the fusion of any two mammalian species whatsoever with lysine residues inserted anywhere in the protein. The specification does not teach one of ordinary skill how to make uricases of the scope of these claims. Claims 16 and 17 simply modify uricase proteins from any source whatsoever with no indication of the sites modified.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Chen, et al. (U), Chua, et al. (AA), Davis, et al. (44), Savoca, et al. (19) or Hishimura, et al. (55) in view of Hershfield, et al. (X-1). Each of the primary references teach the modification of uricase with PEG, with non-deleterious results. Hershfield, et al. teach that PEG can reduce the immunogenicity and prolong the circulating life of enzymes and that more PEG can be introduced into an enzyme by replacing Arg with Lys. It would have been obvious to one of ordinary skill in the art to use the teachings of the primary references that non-deleterious PEG can be introduced into uricase along with the teaching of Hershfield that more PEG can be introduced into enzymes by replacing Arg with Lys to replace Arg with Lys residues with the expectation that the modified enzyme molecules would have PEG introduced at non-deleterious sites. The motivation would have been to produce more useful uricase enzymes. It is pointed out that the instant claims do not specify what the source of the uricase is or where the Lys residues are introduced.

Applicants submitted 4 references for consideration but did not submit another PTO-1449 listing them. In the spirit of cooperation and to move the instant application further towards allowance, the examiner has listed them on the enclosed PTO-892.

Claim 5 is allowed. Claims 3-4, 11, 13 and 15 are objected to as being dependent upon a rejected base claim.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose

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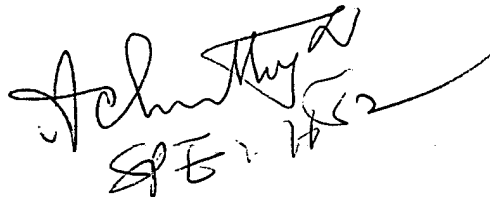
telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Charles L. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
January 21, 2005

  
Ponnathapura Achutamurthy  
SPE: H52